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TITLE: Do Capacitively Coupled Electric Fields Accelerate Tibial Stress Fracture Healing?

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13. ABSTRACT (Maximum 200 Words)

A convenience sample based on availability of tibial stress fracture cases at local Sports Medicine Clinics will be selected over 2-3 years until forty subjects (20 male, 20 female) have been treated. The study is designed to be able to determine if electric field stimulation accelerates the healing of tibial stress fracture and whether there are gender effects. Only posteromedial mid to distal third and proximal medical tibial condylar stress fractures will be investigated. Four imaging approaches will be used at diagnosis (radiographs, bone scan, MRI and CT). All subjects will be identically treated in a double blind fashion using active or passive electric field stimulator devices that apply a sinusoidal wave of 3-6 V, 60 KHz, 5-10 mA, wearing the units for 15-20 hours per day, primary at night, and other standardized rehabilitation treatments, until healed and not longer then 6 months. Subjects will be considered healed when hopping on the affected leg is no longer painful. Only MRI will be used for follow-up studies. A grading system will be developed for each of the diagnostic methods and compared to the ability of the MRI grading system to predict time to recovery.

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Table of Contents

INTRODUCTION

This placebo-controlled study is designed to determine if electric field stimulation will accelerate the healing of tibial stress fractures. Additionally a stress fracture severity grading system is to be developed for four different diagnostic imaging techniques (plain films, nuclear medicine scans, MRI and CT). The purpose of the imaging study is to determine the most cost effective approach to tibial stress fracture diagnosis and the most effective technique to predict time to healing. Twenty male and twenty female subjects will be recruited in order to discriminate gender effects. All subjects are treated identically in a double blind fashion using active or inactive electric field stimulator devices that apply a sinusoidal wave of 3-6 V, 60 KHz, 5-10 mA. Subjects wear the units for 15-20 hrs/day until healed, with a maximum treatment time of 6 months. Subjects are considered healed when hopping on the affected limb is no longer painful.

BODY

The relevant 2002 and 2003 activities in the Statement of Work include:

1. Recruit and treat ~10 subjects 2002 and 10 subjects 2003
2. Prepare interim report

Ongoing Activities include:

1. Collect data, including: subjects consenting, evaluation, consultation and data collection (Food Frequency and Activity History Questionnaires), radiology appointment making, OrthoPak training, subject monitoring, bone density scans
2. Liase with referring clinicians

Problems in accomplishing timeline tasks

The move of the Primary Investigator (Beck) to Griffith University, Australia prompted a Protocol review by USA HSRRB. Recruitment was suspended between February 2002 and March 2003 while the USA HSRRB process ran its course. As the process was very prolonged, our recruitment schedule has understandably suffered. Since the 2002 report we have collected data on a further 13 subjects.

KEY RESEARCH ACCOMPLISHMENTS

- Data collection on 27 subjects in total has been completed (9 at Stanford University and 18 at Griffith University)

SUBJECT #	SEX	AGE	PRIMARY SPORT	TREATMENT TIME (days)	RECRUITING UNIVERSITY
1	Female	32	Running	18	Stanford University
2	Male	35	Running	19	Stanford University
3	Female	46	Running	23	Stanford University
4	Female	16	Running	25	Stanford University
5	Male	30	Running	14	Stanford University

6	Male	22	Running	14	Stanford University
7	Male	18	Running	21	Stanford University
8	Female	33	Running	18	Stanford University
9	Male	19	Running	6	Stanford University
10	Male	23	Running	23	Griffith University
11	Female	21	Aerobics	2	Griffith University
12	Female	18	Sprinting	25	Griffith University
13	Female	21	Sprinting	18	Griffith University
14	Female	34	Running	37	Griffith University
15	Female	18	Running	12	Griffith University
16	Female	22	Running	Released from study after failure to follow protocol.	Griffith University
17	Male	37	Running	7	Griffith University
18	Male	37	Running	6	Griffith University
19	Male	33	Triathlete	17	Griffith University
20	Male	25	Running	8	Griffith University
21	Male	25	Running	8	Griffith University
22	Female	34	Triathlete	17	Griffith University
23	Female	23	Step aerobics	19	Griffith University
24	Female	32	Running	17	Griffith University
25	Male	21	Boxing/running	15	Griffith University
26	Male	21	Boxing/running	16	Griffith University
27	Male	42	Running	9	Griffith University

- Subject data remains blinded from investigators until the end of the study
- Review of imaging and grade scale development will occur by three independent radiologists upon completion of full data set

REPORTABLE OUTCOMES

- No reportable outcomes to date (devices are blinded)

CONCLUSIONS

- No reportable conclusions to date

REFERNCES

NA

APPENDICES

NA